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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/719,889 | 02/21/2001 | Earl R. Owen | 12724-002001 | 6045 |

7590 05/20/2003

Fish & Richardson
Suite 500
4350 La Jolla Village Drive
San Diego, CA 92122

EXAMINER

CHISM, BILLY D

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,889

Applicant(s)

OWEN ET AL.

Examiner

B. Dell Chism

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19-22 and 24-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 19-22 and 24-42 is/are rejected.
- 7) ☒ Claim(s) 5 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Paper No. 9, filed 04 March 2003. Claims 1-16, 19-22 and 24-42 are pending and under consideration. Applicants canceled claims 17-18 and 23.

1. Claims 5 and 41 objected to because of the following informalities: claim 5 misspelled "fluorescent isothiocyante" wherein both words are misspelled and should be amended to read "fluorescein isothiocyanate"; claim 41 misspelled "fibrogen" wherein the word is misspelled and should be amended to read "fibrinogen." Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

2. Claims 1-16, 19-22 and 24-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 is rejected for the indefinite recitation of the phrase "having a predetermined shape." This phrase could mean that it is not yet shaped, but the future shape has been decided and will be physically applied at another time.

4. Claims 1 and 11-12 are indefinite for the recitation of "at least partially denatured", wherein it is not clear what amount of denaturing meets the requirement for the limitation, i.e., what if the inner middle of the composition was denatured yet no surface area was denatured, then the denatured aspect of the solder would be irrelevant? An example of a working product claim for the instant invention is, "A previously shaped biomolecular solder comprising a pre-

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denatured proteinaceous substance.” Although this example does not recite the other aspects of the instant claim 1. Applicants should realize that the portions not in the above recited example, would be best served in a method of making claim set, not in a product claim as they have no real influence on the invention of claim 1 which is a final product.

5. Claims 2, 31 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2, 31 and 39 do not further limit the invention of claim 1. It is clear from reading claim 1 that the solder comprises a proteinaceous substance that inherently means it contains a protein base of some length and or mixture. Claims 2, 31 and 39 are rejected for the indefinite recitation of the phrase “or an analogue thereof.” A protein analogue does not necessarily have to be a protein and since the solder requires a proteinaceous substance, there cannot be just an analogue thereof. Furthermore, it is unclear as what the metes and bounds of the limitation are regarding the analogues thereof.

6. Claims 3-10, 13-16, 19-22, 24-30, 32-38 and 40-42 are rejected for depending from rejected claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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8. Claims 1-7, 10-16, 19, 27-29, 31-34 and 39-42 rejected under 35 U.S.C. 102(e) as being anticipated by Lauto *et al.* 2001 (US 6,323,037 B1).

Lauto *et al.* discloses a biomolecular solder comprising a proteinaceous substance that is hydrated and partially denatured for malleability for better performance of the solder for later application and with adjuvants and growth factors (column 2 line 18 through column 5 line 19). Lauto *et al.* also discloses methods of preparing with use of solvents, dyes and thermal energy sources, and then the application to tissue in need of repair (see Examples 1-2 column 5 line 44 through column 8 line 11).

Conclusions

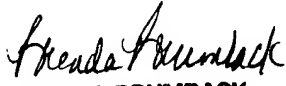
No claims are allowed. Due to new grounds for rejection, this action is NON-FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism
19 May 2003


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600